

## CLAIMS

What is claimed is:

1. A device for guiding medical procedures, comprising:  
at least one subject-specific article comprising at least one reference contour dimensioned to follow a contour of an exterior surface portion of a subject to be treated, said article rigidly attachable to said surface portion, wherein said subject-specific article provides a customized spatial reference for alignment of a preplanned medical procedure to one or more target regions of said subject.
2. The device of claim 1, wherein said article is directly attachable to skin of said subject, exclusive of any protruding fasteners.
3. The device of claim 1, wherein said article includes at least one fastener attached thereto, said fastener for protruding onto or into a surface of said subject.
4. The device of claim 3, wherein said article includes at least one structure for varying a length of said fastener protruding from said article.
5. The device of claim 1, wherein said article includes at least one opening for access to said surface portion, further comprising a probe guide emerging from said opening.

6. The device of claim 5, wherein said probe guide is oriented at a predetermined angle with respect to said article for guidance to said opening or embedded regions under said opening aligned with said probe guide.

7. The device of claim 5, wherein an angle of said probe guide emerging from said opening is adjustable.

8. The device of claim 6, further comprising at least one structure for directing a biopsy or incision depth attached to said article.

9. The device of claim 1, wherein said reference article includes at least one opening for access to said surface portion, further comprising at least one custom skin clip or retractor for attachment along a periphery of said opening.

10. A method for guiding a medical procedure, comprising the steps of:  
providing at least one subject-specific article comprising at least one reference contour dimensioned to follow a contour of an exterior surface portion of a subject to be treated, said article rigidly attachable to said surface portion, wherein said article provides a customized spatial reference for alignment of a preplanned medical procedure to one or more target regions of said subject;

placing said article on said subject; and

performing a medical procedure on said target region, guided at least in part by said subject-specific article.

11. The method of claim 10, wherein said procedure comprises radiotherapy or surgery.

12. A system for performing a medical procedure, comprising:  
at least one subject-specific article comprising at least one reference contour dimensioned to follow a contour of an exterior surface portion of a subject to be treated, said article rigidly attachable to said surface portion, wherein said article provides a customized spatial reference for alignment of a preplanned medical procedure to one or more target regions of said subject; and  
a therapeutic, diagnostic or surgical device, wherein said device is guided to said target region at least in part by said subject-specific article.

13. The system of claim 12, wherein said subject-specific article comprises a plurality of external reference markers.

14. The system of claim 13, wherein said reference markers are optical markers.

15. The system of claim 12, wherein said article includes at least one opening for access to said surface portion, further comprising a probe guide emerging from said opening.

16. A system for forming a device comprising a subject-specific article comprising at least one reference contour for guiding a medical procedure, comprising:

computing structure for providing 3-dimensional data representing a subject-specific article comprising a reference contour dimensioned to replicate a contour of an exterior surface portion of a subject to be treated; and

a machine for forming said device from said 3-dimensional data.

17. The system of claim 16, wherein said contour of said subject to be treated is computed from a 3-dimensional planning image of said subject.

18. The system of claim 16, wherein said machine is a rapid prototyping machine.